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Application Number

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TRANSMITTAL
FORM

Filling Date
Nov. 24, 2003

First Named Inventor

Art Unit

Examiner Name

Attorney Docket Number

Total Number of Pages in This Submission

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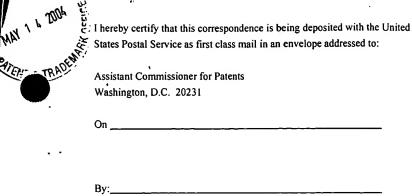
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				ENG	CLOSURES (Che	eck all that apply	<i>)</i>		<u></u>	
Fee Transmittal Form Fee Attached Amendment/Reply After Final Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Disclosure Statement Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53			<u> </u>	Drawing(s) Licensing-related Papers Petition Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence Address to Techn Appeal C (Appeal N Proprieta Proprieta Status Le			to Technolo Appeal Com of Appeals a Appeal Com (Appeal Notic Proprietary Status Lette Other Enclo Identify belo	er sure(s) (plea	C) o Board nces o TC y Brief)	
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sufficie	I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.									
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Branscum, et al.

Application No.: 10/721115

Filed: November 24, 2003

For: Method and apparatus for evaluation

of sleep disorders

Examiner:

Unassigned

Art Unit:

Unassigned

INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR §1.97 and

§1.98

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Page 2

It is further noted that the categories provided for the information and references are not represented as being definitive and/or mutually exclusive. Additional categorizations are possible.

Applicant believes that <u>no fee is required</u> for submission of this statement, since it is being submitted prior to the first Office Action.

Respectfully submitted,

John Sotos Applicant

PTO/SB/08A (10-01) Approved for use through 10/31/2002. OMB 0551-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Index the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMR control number. ADEM Substitute for form 1449A/PTO Complete if Known **Application Number** 10/721115 Filing Date First Named Inventor

Art Unit

Examiner Name

Attorney Docket Number

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

			U.S. PATENT DO	DCUMENTS	
Examiner	Cite No.1	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US- 4,982,738	01-08-1991	Griebel	
	AB	US- 5,275,159	01-04-1994	Griebel	
	AC	US- 5,671,733	09-30-1997	Raviv	
	AD	US- 5,782,240	07-21-1998	Raviv	
	AE	US- 5,792,067	08-11-1998	Karell	
	AF	US- 5,797,852	08-25-1998	Karakasoglu	
	AG	US- 5,853,005	12-29-1998	Scanlon	
	AH	US- 5,879,313	03-09-1999	Raviv	
	Al	US- 5,961,447	10-05-1999	Raviv	
	AJ	US- 6,045,514	04-04-2000	Raviv	
	AK	US- 6,120,441	09-19-2000	Griebel	
	AL	US- 6,168,568	01-02-2001	Gavriely	
	AM	US- 6,171,258 B1	01-09-2001	Karakasoglu	
	AN	US- 6,201,982 B1	03-13-2001	Menkes	
	AO	US- 6,213,955 B1	04-10-2001	Karakasoglu	
	AP	US- 6,261,238 B1	07-17-2001	Gavriely	
	AQ	US-Application Ser. No. 040937		Westbrook	
	AR	Lus-			

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite	Foreign Patent Document		Publication Date MM-	Name of Patentee or	Pages, Columns, Lines,			
	No.1	Country Code	Number ⁴	Kind Code ⁵ (if known)	DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁶	
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Substitut	e for form 1449A/PTO				Complete if Known		
•				Application Number	10/721115		
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Sheet	2	of	6	Attorney Docket Number			

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite	Foreign Patent Document				Name of Patentee or	Pages, Columns, Lines,		
	No.1	Country Code	Number ⁴	Kind Code ⁵ (if known)	Publication Date MM- DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T⁵	
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INFORMATION DISCLOSURE	Filing Date			
STATEMENT BY APPLICANT	First Named Inventor			
	Art Unit			
(use as many sheets as necessary)	Examiner Name			
Sheet 3 of 6	Attorney Docket Number			

	•	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
	вс	AASM (AMERICAN ACADEMY OF SLEEP MEDICINE TASK FORCE). Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. Sleep. 1999;22:667-689.	
	BD	A. BAR, et al. Evaluation of a portable device based on peripheral arterial tone for unattended home sleep studies. Chest. 2003;123:695-703.	
	BE	T. BOND. Evaluation and diagnosis of sleep-disordered breathing. Oral Maxillofacial Surg Clin N Am. 2002;14:293-296.	
	BF	C. BOOTH-THOMAS. The see-it-all chip. Time Magazine. 2003 Sept. 22;162(12). Downloaded as 5 pages from http://www.time.com/time/globalbusiness/printout/0,8816,485764,00.html on Oct. 22, 2003.	
-	BG	R. CARTWRIGHT. What's new in oral appliances for snoring and sleep apnea: an update. Sleep Medicine Reviews. 2001;5:25-32.	
	ВН	A.L. CHESSON, et al. Practice parameters for the indications for polysomnography and related procedures. Sleep. 1997;20:406-22.	
	ВІ	N.J. DOUGLAS. Home diagnosis of the obstructive sleep apnoea/hypopnoea syndrome. Sleep Med Rev. 2003;7:53-9.	
	ВЈ	R. FERBER, et al. Portable Recording in the Assessment of Obstructive Sleep Apnea. Sleep. 1994;17:378-392.	
-	ВК	K.A. FERGUSON. The role of oral appliance therapy in the treatment of obstructive sleep apnea. Clin Chest Med. 2003;24:355-364.	
	BL	W.W. FLEMONS. Home diagnosis of sleep apnea: a systematic review of the literature: an evidence review cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. Chest. 2003;124:1543-79 and 14 pages of supplementary material published online.	
	вм	J.L. GOODWIN, et al. Feasibility of using unattended polysomnography in children for research report of the Tucson Children's Assessment of Sleep Apnea Study (TuCASA). Sleep. 2001;24:937-944.	
	BN	L. GROTE, et. al. Therapy with nCPAP: incomplete elimination of sleep related breathing disorder. Eur Resp J. 2000;16:921-7.	
	во	C.K. LI, W.W. FLEMONS. State of home sleep studies. Clin Chest Med. 2003;24:283-295.	
	ВР	M.R. LITTNER, J.W. SHEPARD. Recommendations for research into measurement and classification of sleep disordered breathing: gazing into the crystal ball. Sleep. 1999;22:665-666.	
	BQ	N. MESLIER, et al. Validation of a suprasternal pressure transducer for apnea classification during sleep. Sleep. 2002;25:753-7.	

Examiner	Date	
Signature	Considered	

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	Art Unit			
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Sheet 4 of 6	Attorney Docket Number			

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *.	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	T²
	BR	N. NETZER, et al. Overnight pulse oximetry for sleep-disordered breathing in adults: a review. Chest. 2001;120:625-633.	
	BS	P.E. PEPPARD, et al. Prospective study of the association between sleep-disordered breathing and hypertension. N Engl J Med. 2000;342:1378-1384.	
	вт	S.F. QUAN, J.C. GILLIN. New definitions of sleep disordered breathing not yet a mandate for change in clinical practice. Sleep. 1999;22:662.	
	ви	S.D. ROSS, et al. Systematic review and meta-analysis of the literature regarding the diagnosis of sleep apnea. Sleep. 2000;23:519-532.	
	BV	N. TACHIBANA, et al. A comparison of sleep laboratory activity in the United States and Japan. Sleep. 2002;25(Suppl.):A47.	
<u> </u>	BW	M-L. WALKER-ENGSTROM, et al. 4-year follow-up of treatment with dental appliance or uvulopalatopharyngoplasty in patients with obstructive sleep apnea. Chest. 2002;121:739-746.	
	вх	T. YOUNG, et al. Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women. Sleep. 1997;20(9):705-6.	
	BY	T. YOUNG, et al. Epidemiology of obstructive sleep apnea: a population health perspective. Am J Respir Crit Care Med. 2002;165:1217-1239.	
	BZ	CATEGORY 1 FOLLOWS: USE OF SNORING SOUNDS IN DETECTING SLEEP-DISORDERED BREATHING	
	ВАА	J.H. FICKER, et al. Evaluation of a portable recording device (Somnocheck) for use in patients with suspected obstructive sleep apnoea. Respiration. 2001;68:307-12.	
	ввв	C.J. GRIFFITHS, et al. A video system for investigating breathing disorders during sleep. Thorax. 1991;46:136-140.	
	всс	F.G. ISSA, et al. Digital monitoring of obstructive sleep apnea using snoring sound and arterial oxygen saturation. Sleep. 1993;16:S32.	
	BDD	F.G. ISSA, et al. Digital monitoring of sleep disordered breathing using snoring sound and arterial oxygen saturation. Am Rev Respir Dis. 1993;148:1023-1029.	
	BEE	A.W. McCOMBE, et al. An acoustic screening test for obstructive sleep apnea. Clinical Otology. 1995;20:348-351.	
	BFF	T. PENZEL, et al. MESAM: a heart rate and snoring recorder for detection of obstructive sleep apnea. Sleep. 1990;13:175-182.	
Examiner		Date	

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Examiner	Date	·	
Signature	Considered		

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STATEMENT BY APPLICANT	First Named Inventor		
	Art Unit		
(use as many sheets as necessary)	Examiner Name		
Sheet 5 of G	Attorney Docket Number		

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
	BGG	Remmers sleep recorder, How to set up and use. Downloaded 2 pages on Oct. 31, 2003 from: www.comfortacrylics.com/appliance/resource/protocols/Remmers_instructions.pdf	
	внн	Y. SIVAN, et al. Screening obstructive sleep apnoea syndrome by home videotape recording in children. Eur Respir J. 1996;9:2127-2131.	
	ВІІ	Sleep Solutions Inc. NovaSom QSG Technology Summary. Downloaded 11 pages on July 21, 2002 from: http://www.sleep-solutions.com/phys/phys_novasom_qsg.htm	
	BJJ	SNAP Laboratories LLC. Downloaded 3 pages on July 21, 2002 from: (1) http://www.snaplab.com/home.htm (2) http://www.snaplab.com/mp_demo.htm (3) http://www.snaplab.com/mp_fact.htm	
	вкк	R. STOOHS, C. GUILLEMINAULT. Investigations of an automatic screening device (MESAM) for obstructive sleep apnea. Eur Respir J. 1990;3:823-829.	
	BLL	D.L. VAN BRUNT, et al. Intensity pattern of snoring sounds as a predictor for sleep-disordered breathing. Sleep. 1997;20:1151-1156.	
	вмм	J.E.S. WHITE, et al. The use of sound recording and oxygen saturation in screening snorers for obstructive sleep apnea. Clinical Otology. 1994;19:218-221.	
	BNN	CATEGORY 2 FOLLOWS: USE OF TRACHEAL BREATH SOUNDS IN DETECTING SLEEP-DISORDERED BREATHING	
	воо	R.C. BECKERMAN, et al. Tracheal breath sounds for detection of apnea in infants and children. Critical Care Medicine. 1982;10:363-366.	
	ВРР	J. CUMMISKEY, et al. The detection and quantification of sleep apnea by tracheal sound recordings. Am Rev Respir Dis. 1982;126:221-224.	
	BQQ	K.A. EAST, T.D. EAST. Computerized acoustic detection of obstructive apnea. Comput Meth Prog Biomedicine. 1985;21:213-220.	
~	BRR	J.P. HEEMELS, et al. Tracheal sound detector. Med Biol Eng Comput. 1986;24:182-185.	
	BSS	W. HIDA, et al. Home sleep monitor for detecting apnea episodes by nasal flow and tracheal sound recordings. Tohoku J Exp Med. 1988;156(Suppl.):137-142.	
	втт	W. HIDA, et al. Prevalence of sleep apnea among Japanese industrial workers determined by a portable sleep monitoring system. Respiration. 1993;60:332-337.	
	вии	P.E. KRUMPE, J.M. CUMMISKEY Use of laryngeal sound recordings to monitor apnea. Am Rev Respir Dis. 1980;122:797-801.	

Examiner	•	Date	
Signature		Considered	

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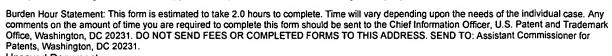
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		Examiner Name			
Sheet	6	of	6	Attorney Docket Number	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	BVV	R.P. MARSH, et al. Recorder for assessment of upper airway disorders. Otolaryngol Head Neck Surg. 1983;91:584-585.	
	BWW	N. MESLIER, et al. Tracheal sound recordings detect and quantify sleep apnea, hypopnea and snores. Am Rev Respir Dis. 1986;113:A55.	
	вхх	J. PEIRICK, J.W. SHEPARD Jr. Automated apnoea detection by computer: analysis of tracheal breath sounds. Med Biol Eng Comput. 1983;21:632-635.	
	BYY	W.P. POTSIC. Relief of upper airway obstruction by adenotonsillectomy. Otolaryngol Head Neck Surg. 1986;94:476-480.	
	BZZ	W.P. POTSIC. Comparison of ploysomnography and sonography for assessing regularity of respiration during sleep in adenotonsillar hypertrophy. Laryngoscope. 1987;97:1430-1437.	
	ВААА	A. SANNA, et al. Interet su suivi des bruits respiratoires tracheaux dans le diagnostic de dysrythmies respiratoires nocturnes. Acta Clinica Belgica. 1991;46:159-164	
	BBB8	A.J. WILLIAMS, et al. A new computer program for storage and analysis of sleep study data. FASEB Journal. 1988;2:A1511.	
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Signature	Considered		

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